Center for Vaccine Ethics and Policy
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Vaccines: The Week in Review
14 July 2012
Center for Vaccine Ethics & Policy (CVEP)

This weekly summary targets news, announcements, articles and events in global vaccines ethics and policy gathered from key governmental, NGO, international organization and industry sources, key peer-reviewed journals and other media channels This summary proceeds from the broad base of themes and issues monitored by the Center for Vaccine Ethics & Policy in its work, and is not intended to be exhaustive in its coverage. Vaccines: The Week in Review is also posted in pdf form and as a set of blog posts at http://centerforvaccineethicsandpolicy.wordpress.com/. This blog allows full-text searching of over 3,000 entries..

Comments and suggestions should be directed to
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[Editor's Note: Last week we provided the full text of a GAR update: Undiagnosed illness in Cambodia – update 6 July 2012
http://www.who.int/csr/don/2012_07_06a/en/index.html
The following announcement concludes the joint investigation undertaken:

Severe complications of hand, foot and mouth disease (HFMD) caused by EV-71 in Cambodia – conclusion of the joint investigation

Extract from announcement

13 July 2012 - The investigation into the illnesses and deaths in Cambodia, which mainly affected very young children, concluded that a severe form of hand, foot and mouth disease (HFMD) was the cause in the majority of cases reported to the Ministry of Health.

Samples from a total of 31 patients were obtained and tested for a number of pathogens by Institut Pasteur du Cambodge. Most of these samples tested positive for enterovirus 71 (EV-71) which causes HFMD. A small proportion of samples also tested positive for other pathogens including Haemophilus Influenzae type B and Streptococcus suis. It was not possible to test all the patients as some of them died before appropriate samples could be taken.

The investigation included:
- a thorough review of the hospital records of the patients from Kantha Bhopa hospital as well as from other hospitals;
- laboratory tests;
- active follow-up with the affected families by the local Rapid Response Teams (RRT); and
- evaluation of the data from the national surveillance system…

http://www.who.int/csr/don/2012_07_13/en/index.html

The Democratic People's Republic of Korea launched the pentavalent vaccine at a ceremony at the People Palace of Culture in Pyongyang on 12 July 2012. This vaccine introduction "will mean that now around 350,000 children under one will be vaccinated every year against Hib" in addition to other diseases. The DPR Korea "will continue to co-finance the cost of GAVI vaccines at US$834,000 from 2012 to 2015." GAVI said that, working closely with WHO and UNICEF which have staff in the country, it has supported DPR Korea since 2001 and "has helped the country strengthen its immunisation systems, including a major upgrade of the cold chain system to ensure sufficient space for introduction of pentavalent and potentially other new vaccines such as rotavirus and pneumococcal…" The announcement noted that "DPR Korea is one of the few countries in the WHO South-East Asia Region to achieve consistently high coverage for vaccines. There have been no reported cases of poliomyelitis since 1996 and no measles since the mass vaccination campaign in April 2007." http://www.gavialliance.org/library/news/gavi-features/2012/dpr-korea-introduces-pentavalent-vaccine/

The World Bank's Board approved an International Development Association (IDA) credit of US$95 million for the Nigeria Polio Eradication Support Project, which will "help the country to achieve and sustain at least 80% polio immunization across all states, supporting the eventual eradication of the disease from Nigeria." The project will finance roughly 655 million doses of oral polio vaccine for children under age five across Nigeria, with a special focus on the northern states where polio is more prevalent. The World Bank has worked with Nigeria's National Primary Health Care Agency since 2003 to ensure timely vaccine supply. The project continues a "buy-down" arrangement by which the Gates Foundation, the US Centers for Diseases Control and Prevention, and Rotary International (via the UN Foundation), will repay the loan's present value when pre-agreed results are met. Of the World Bank's lending commitments to Nigeria for polio from 2003 to 2012—a total of $195 million—Nigeria has already qualified for a 70 percent buy-down. http://web.worldbank.org/WBSITE/EXTERNAL/NEWS/0,,contentMDK:23240730~pagePK:34370~piPK:34424~theSitePK:4607,00.html

NIH said it awarded US$31 million in first-year funding to Duke University and Scripps Research Institute to lead a new consortium: the Centers for HIV/AIDS Vaccine Immunology & Immunogen Discovery (CHAVI-ID). The funding is from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The initiative is projected to receive up to US$186 million or more over the next six years with a goal "to accelerate HIV vaccine development by supporting multidisciplinary research into immune responses that prevent or contain HIV infection and generating model vaccine components that can induce these protective immune responses." CHAVI-ID is described as a consortium of

researchers at universities and academic medical centers which will build on advances made in several laboratories, including the Center for HIV/AIDS Vaccine Immunology (CHAVI) based at Duke. CHAVI's seven-year funding award from NIAID ended in June. NIAID Director Anthony S. Fauci, M.D. commented, "In recent years, considerable progress has been made in identifying antibodies that can prevent a broad range of HIV strains from infecting human cells. CHAVI-ID will attempt to understand how those antibodies and other immune responses work to protect against HIV infection, providing scientists with a rational foundation for designing what we hope will be an effective HIV vaccine."
More at: http://www.nih.gov/news/health/jul2012/niaid-13.htm

Conference: *The International AIDS Conference*
22-27 July 2012; Washington DC
Overview
"The International AIDS Conference is the premier gathering for those working in the field of HIV, as well as policy makers, persons living with HIV and other individuals committed to ending the pandemic. It is a chance to assess where we are, evaluate recent scientific developments and lessons learnt, and collectively chart a course forward.
"The AIDS 2012 programme will present new scientific knowledge and offer many opportunities for structured dialogue on the major issues facing the global response to HIV. A variety of session types – from abstract-driven presentations to symposia, bridging and plenary sessions – will meet the needs of various participants. Other related activities, including the Global Village, satellite meetings, exhibitions and affiliated independent events, will contribute to an exceptional opportunity for professional development and networking."
http://www.aids2012.org/Default.aspx?pageId=305

The Global Fund released an analysis of audits and investigations by its Office of the Inspector General which showed "that 3.0 percent of funding audited or investigated between 2005 and 2012 had been misspent, fraudulently misappropriated or inadequately accounted for." Cees Klumper, Chief Risk Officer at the Global Fund who conducted the analysis, said, "We do not tolerate any misuse of funds, no matter how minor. Although some of these funds were misspent, and are just ineligible expenses, a small percentage of funds are misappropriated through fraud. We actively pursue and expose all such cases." The Office of the Inspector General is "fully independent and reports directly to the Board" and, since it was established in 2005, has compiled 28 reports on audits and investigations that it has carried out in 27 countries, where a total of $3.8 billion has been disbursed, approximately 23 percent of all disbursements that the Global Fund has made to date.
The analysis showed that, cumulatively, the 3 percent of the funding that not spent in compliance with the grant agreements included:
- Ineligible expenses – or activities not covered by the grant agreements – 1.1 percent
- Inadequately substantiated due to poor or missing documentation – 1.1 percent
- Fraud – 0.5 percent

- Failed to report funds as required – 0.3 percent

The Global Fund noted that the analysis "…did not represent a comprehensive accounting of all misspent funds. Instead, the analysis is a factual rendering of the percentages of funding that had been determined by Global Fund audits and investigations to be ineligible, fraudulently misappropriated or inadequately accounted for." Further, the release "cautioned that audits and investigations conducted…tend to focus on high-risk areas and on grants where specific risks have been identified, and that it was "…not possible to extrapolate to say that this reflects an accurate picture of misused funds…Our audits and investigations are not a representative sampling of all Global Fund grants."
http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-07-10_Global_Fund_Releases_an_Analysis_of_Audits_and_Investigations_2012/

The London Summit on Family Planning, co-hosted by the UK Government's Department for International Development and the Bill & Melinda Gates Foundation, was held in London last week, resulting in a "new set of commitments…by more than 150 leaders from donor and developing countries, international agencies, civil society, foundations and the private sector…(to extend" voluntary family planning services to reach an additional 120 million women and girls in the world's poorest countries by 2020."
http://www.gatesfoundation.org/press-releases/Pages/summit-women-global-health-120711.aspx

WHO: *Questions and answers on new facts and figures on vaccines and the global mercury treaty*

[Initial question from document]

Q. Are there new data on the human health impact of thiomersal in vaccines?

A. Yes, an independent scientific advisory body convened by WHO, the Global Advisory Committee on Vaccine Safety (GACVS), reviewed the latest data on 7 June 2012. The report of the meeting will be published in the WHO Weekly Epidemiological Record on 20 July 2012 (http://www.who.int/wer/2012/en/). The Committee concluded that numerous well---designed Epidemiological studies conducted in many countries have failed to find a causal relationship Between prenatal, neonatal, or postnatal exposures to thiomersal in vaccines and a host of Neuropsychological outcomes, including autism.

The small number of studies which had suggested an association had significant flaws in their design and underlying assumptions, thus invalidating their conclusions. Other studies conducted Since 2008, including analysis of mercury in blood and hair, provided confirmation that the half --- life of thiomersal (ethyl mercury) was much shorter than that of methyl mercury.

Document pdf:
http://www.who.int/entity/immunization/newsroom/QAs_new_facts_figures_thiomersal_June_2012.pdf

Guidelines on regulatory expectations related to the elimination, reduction or replace of thiomersal in vaccines (2004)
http://www.who.int/entity/biologicals/publications/trs/areas/vaccines/thiomersal/Annex%204%20(95-102)TRS926thiomersal.pdf

INC4: The fourth session of the Intergovernmental Negotiating Committee to prepare a global legally binding instrument on Mercury (INC4) was held in Punta del Este, Uruguay, from 27 June to 2 July 2012.
http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC4/tabid/3470/Default.aspx

WHO Fact Sheet: Vaccine success story: congenital rubella syndrome
13 July 2012 -- A newly released WHO fact sheet explains how vaccination has drastically reduced congenital rubella syndrome and describes the global strategy to achieve elimination. An estimated 110 000 babies are born with congenital rubella syndrome every year. While the illness is generally mild in children, it has serious consequences in pregnant women causing fetal death or congenital defects.
Read the rubella fact sheet
Read the Global Measles and Rubella Strategic Plan

WHO: *GIN – Global Immunization News 30 June 2012*
http://www.who.int/entity/immunization/GIN_June_2012.pdf
This issue includes:
SUMMARY TABLES OF WHO ROUTINE IMMUNIZATION RECOMMENDATIONS
The Summary Tables of WHO Routine Immunization Recommendations have been updated as of May 31, 2012 to reflect:
- The new WHO Vaccine Position Paper on Pneumococcal vaccines (published in the WHO Weekly epidemiological record (WER) 6 April 2012); and
- The lifting of the age restrictions for Rotavirus vaccines recommended by SAGE at their April 2012 Meeting (See SAGE Meeting Report in WER 25 May 2012)
- The revised version of the Summary Tables can be downloaded from the WHO website and are also available in French (Note: French version of Table 3 will be available soon).
The Summary Tables are intended for use by national immunization managers and key decision-makers, chairs and members of national advisory committees on immunization, and partner organizations, including industry.
http://www.who.int/immunization/policy/immunization_tables/en/index.html
GLOBAL VACCINE SAFETY BLUEPRINT (WHO/IVB/12.07)
This IVB document is now online. The Global Vaccine Safety Blueprint is a WHO strategic document that proposes new approaches to a consortium for strengthening vaccine pharmacovigilance systems in low-and middle-income countries.
http://extranet.who.int/iris/restricted/bitstream/10665/70919/1/WHO_IVB_12.07_eng.pdf

The **Weekly Epidemiological Record (WER) for 13 July 2012**, vol. 87, 28/29 (pp 261–276) includes: WHO position paper on hepatitis A vaccines – June 2012
http://www.who.int/entity/wer/2012/wer8728_29.pdf

WHO: Hepatitis A vaccination should be part of a comprehensive plan for prevention and control of viral hepatitis
Media Release Extract

13 July 2012 - In an updated position paper, published in the Weekly Epidemiological Record today, WHO recommends that hepatitis A vaccination be integrated into national immunization schedule for children over the age of one, if indicated on the basis of acute hepatitis A incidence and consideration of cost-effectiveness.

Vaccination should particularly be considered in countries with improving socioeconomic status when there is a change from high to intermediate endemicity and when the age of infection shifts to older age group thus increasing the risk of more severe disease and mortality. In these situations vaccination is likely to be cost-effective. In highly endemic countries where hepatitis A virus is widespread, almost all persons are infected with hepatitis A virus in early childhood, when the infection is asymptomatic or results in very mild disease. In these countries, large-scale vaccination programmes are not recommended.

Vaccination against hepatitis A should be part of a comprehensive plan for the prevention and control of viral hepatitis, including measures to improve hygiene and sanitation and measures for outbreak control. Targeted vaccination of high-risk groups should be considered in low and very low endemicity settings to provide individual health benefits. Groups at increased risk of hepatitis A include travellers to areas of intermediate or high endemicity, those requiring life-long treatment with blood products, men who have sex with men, workers in contact with non-human primates, and injection drug users. In addition, patients with chronic liver disease are at increased risk for fulminant hepatitis A and should be vaccinated…
More at:
http://www.who.int/immunization/newsroom/newsstory_hepa_vaccine_control_viral_hepatitis/en/index.html

Twitter Watch *[accessed 14 July 2012 – 13:42]*
Items of interest from a variety of twitter feeds associated with immunization, vaccines and global public health. This capture is highly selective and is by no means intended to be exhaustive.

GAVI Alliance @GAVIAlliance
There is still plenty of time to give feedback on @GAVIAlliance country by country approach. Share your thoughts! http://ht.ly/ceIJq
6:49 AM - 14 Jul 12

World Bank @WorldBank
News: World Bank to support Nigeria's final push to eradicate #polio http://bit.ly/NhTnEI

4:51 PM - 13 Jul 12

IVAC at JHSPH @IVACtweets
Did you know scientists discovered Streptococcus pneumoniae bacterium 131 years ago? Find out what's happened since: http://bit.ly/NeFEwl
Retweeted by History of Vaccines
2:37 PM - 12 Jul 12

IVAC at JHSPH @IVACtweets
New! @HuffingtonPost blog from @OrinLevine. 4 ways that investment bankers can help developing countries http://huff.to/PPU21h #FPSummit
4:50 PM - 12 Jul 12

CDC Global Health @CDCGlobal
With CDC help, Burkina Faso has vaccinated 17M kids for #polio, 2.4M kids for #measles & >12M ppl for #meningitis. http://go.usa.gov/w8X
Retweeted by M&R Initiative
1:54 PM - 11 Jul 12

IAVI @AIDSvaccine
IAVI congratulates @ScrippsResearch @Duke_Medicine on award of @NIAIDnews grants to support #HIV #vaccine R&D http://bit.ly/Mj870D #AIDS2012
2:58 PM - 11 Jul 12

Amanda Glassman @glassmanamanda
HHA declaration on value for money, accountability and sustainability in health in Africa - music to my ears... http://www.hha-online.org/hso/system/files/tunis_declaration_english_july6.pdf
10:52 AM - 10 Jul 12

Reports/Research/Analysis/Book Watch

Vaccines: The Week in Review has expanded its coverage of new reports, books, research and analysis published independent of the journal channel covered in *Journal Watch* below. Our interests span immunization and vaccines, as well as global public health, health governance, and associated themes. *If you would like to suggest content to be included in this service, please contact David Curry at:* *david.r.curry@centerforvaccineethicsandpolicy.org*

NIH Research: Vaccine and antibiotics stabilized so refrigeration is not needed

Extract from media release

Researchers funded by the National Institutes of Health have developed a new silk-based stabilizer that, in the laboratory, kept some vaccines and antibiotics stable up to temperatures of 140 degrees Fahrenheit. This provides a new avenue toward eliminating

the need to keep some vaccines and antibiotics refrigerated, which could save billions of dollars every year and increase accessibility to third world populations.

Vaccines and antibiotics often need to be refrigerated to prevent alteration of their chemical structures; such alteration can result in less potent or ineffective medications. By immobilizing their bioactive molecules using silk protein matrices, researchers were able to protect and stabilize both live vaccines and antibiotics when stored at higher than recommended temperatures for periods far longer than recommended.

The research was led by grantees of NIH's National Institute of Biomedical Imaging and Bioengineering (NIBIB), David Kaplan, Ph.D., and Jeney Zhang, Ph.D. candidate, at Tufts University School of Engineering in Medford, Mass. The National Eye Institute and the National Institute of Dental and Craniofacial Research at NIH also contributed to this research. The researchers reported on their findings in the online issue of Proceedings of the National Academy of Sciences on July 9, 2012.

"This truly exciting development is the culmination of years of creative exploration and research focused on a major problem in the delivery of health care. Dr. Kaplan and his team have done a masterful job at both understanding the key properties of silk, and applying these insights to a global medical challenge," said NIBIB Director Roderic I. Pettigrew, Ph.D., M.D. "This is also a wonderful validation of the type of team science we see in our Biotechnology Resource and Development Centers and their ability to combine cutting edge science in a number of fields to a variety of health needs."

Pettigrew also points out that the next step is to test it in the field.
http://www.nih.gov/news/health/jul2012/nibib-09.htm
[See PNAS citation in Journal Watch below]

Report: *HIV and the Law: Risks, Rights & Health*
Global Commission on HIV and the Law (UNDP)
09 July 2012
"The final report presents a coherent and compelling evidence base on human rights and legal issues relating to HIV."
http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/hiv-and-the-law--risks--rights---health.html
Report pdf:
http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/FinalReport-Risks,Rights&Health-EN.pdf

Report: *Horizon 2025: creative destruction in the aid industry*
Homi Kharas and Andrew Rogerson
ODI (Overseas Development Institute)
July 2012
This paper aims to stimulate debate on the future of the international development architecture and explores how far some of today's major development agencies are likely to be exposed to the resulting pressures to change course, emulate the disruptors or face irrelevance.
Summary [full text]

The global economic landscape has evolved dramatically since 2000: developing and emerging economies have been driving global growth, new sources of development

finance have mushroomed and the diversification of actors, instruments and delivery mechanisms has continued. Transformations in the poverty map and new forces on the supply side of development finance are challenging the international development architecture. This paper aims to stimulate debate on the future of this architecture.

The authors project that, by 2025, the locus of global poverty will overwhelmingly be in fragile, mainly low-income and African, states, contrary to current policy preoccupations with the transitory phenomenon of poverty concentration in middle-income countries. Moreover, a smaller share of industrialised country income than ever before will potentially close the remaining global poverty gap, although direct income transfers are not yet feasible in many fragile country contexts.

Against this backdrop, new institutions, business models and practices are challenging long-established 'aid industry' actors. Agencies providing development finance for improved social welfare, for mutual self-interest in growth and trade and for the provision of global public goods will find that, in each area, disruptors to their programmes may force a change in positioning.

The paper focuses on one such disruptor for each of these three complementary rationales for development cooperation. The key disruptor we discuss in the first area is high-impact philanthropy and non-governmental giving channels; in the second, South–South cooperation combining trade and finance, and blended public–private funding in general; and in the third, the power of climate change finance, particularly its quite different country and project allocation logic.

From this analysis, this paper explores how far some of today's major development agencies are likely to be exposed to the resulting pressures to change course, emulate the disruptors or face irrelevance.

The authors construct an index of vulnerability, presented in a traffic-light ranking, based on recent shares of each agency's operations going to, first, middle-income and low poverty gap countries and, second, purposes linked respectively to social welfare, growth and global public goods, with appropriate weights.

These assessments are offered not as predictions but as possible stress test tools for further, context-specific analysis. The paper ends with questions for further research.

Journal Watch

Vaccines: The Week in Review continues its weekly scanning of key peer-reviewed journals to identify and cite articles, commentary and editorials, books reviews and other content supporting our focus on vaccine ethics and policy. ***Journal Watch*** **is not intended to be exhaustive, but indicative of themes and issues the Center is actively tracking.** We selectively provide full text of some editorial and comment articles that are specifically relevant to our work. Successful access to some of the links provided may require subscription or other access arrangement unique to the publisher.

If you would like to suggest other journal titles to include in this service, please contact David Curry at: david.r.curry@centerforvaccineethicsandpolicy.org

Annals of Internal Medicine
3 July 2012, Vol. 157. No. 1
http://www.annals.org/content/current

[Reviewed earlier; No relevant content]

British Medical Bulletin
Volume 102 Issue 1 June 2012
http://bmb.oxfordjournals.org/content/current
[Reviewed earlier; No relevant content]

British Medical Journal
14 July 2012 (Vol 345, Issue 7865)
http://www.bmj.com/content/345/7865
Analysis
Problems of stopping trials early
BMJ 2012; 344 doi: 10.1136/bmj.e3863 (Published 15 June 2012
Gordon H Guyatt, Matthias Briel, Paul Glasziou, Dirk Bassler, Victor M Montori,
Extract

When interim analyses of randomised trials suggest large beneficial treatment effects, investigators sometimes terminate trials earlier than planned. Gordon H Guyatt and colleagues show how this practice can have far reaching and harmful consequences

In a seminal simulation study published in 1989, Pocock and Hughes showed that randomised control trials stopped early for benefit will, on average, overestimate treatment effects.1 Since then, the warning implicit in this simulation study has been largely ignored.

Fifteen years later, we reported a systematic survey which showed that trials stopped early for benefit—which we will refer to as truncated trials—yield treatment effects that are often not credible (relative risk reductions over 47% in half, over 70% in a quarter), and that the apparent overestimates were larger in smaller trials.2 We subsequently compared effect estimates from all the truncated trials we could identify that had been included in systematic reviews and meta-analyses with the results of non-truncated trials in those same meta-analyses. We found, on average, substantially larger effects in the truncated trials (ratio of relative risks in truncated versus non-truncated of 0.71). Again, we showed an association with the size of the truncated trial: large overestimates were common when the total number of events was less than 200; smaller but important overestimates occurred with 200 to 500 events; and trials with over 500 events showed small overestimates.3

The results of simulation studies and systematic surveys of truncated trials therefore show that when true underlying treatment effects are modest—as is usually the case—small trials that are stopped early with few events will result in large overestimates. Larger trials will still, on average, overestimate effects, and these overestimates may also lead to important spurious inferences. Uncritical belief in truncated trials will often, therefore, be misleading—and sometimes very misleading.

The tendency for truncated trials …

Bulletin of the World Health Organization
Volume 90, Number 7, July 2012, 477-556
http://www.who.int/bulletin/volumes/90/7/en/index.html

[Reviewed earlier]

Cost Effectiveness and Resource Allocation
(Accessed 14 July 2012)
http://www.resource-allocation.com/
[No new relevant content]

Emerging Infectious Diseases
Volume 18, Number 7—July 2012
http://www.cdc.gov/ncidod/EID/index.htm
[Reviewed earlier]

Eurosurveillance
Volume 17, Issue 28, 12 July 2012
http://www.eurosurveillance.org/Public/Articles/Archives.aspx?PublicationId=11678
[No relevant content]

Global Health Governance
Volume V, Issue 2: Spring 2012
[Reviewed earlier]

Globalization and Health
[Accessed 14 July 2012]
http://www.globalizationandhealth.com/
Debate
Models for financing the regulation of pharmaceutical promotion
Joel Lexchin
Abstract (provisional)
Pharmaceutical companies spend huge sums promoting their products whereas regulation of promotional activities is typically underfinanced. Any option for financing the monitoring and regulation of promotion should adhere to three basic principles: stability, predictability and lack of (perverse) ties between the level of financing and performance. This paper explores the strengths and weaknesses of six different models. All these six models considered here have positive and negative features and none may necessarily be ideal in any particular country. Different countries may choose to utilize a combination of two or more of these models in order to raise sufficient revenue. Financing of regulation of drug promotion should more than pay for itself through the prevention of extra unnecessary drug costs and the avoidance of adverse health effects due to inappropriate prescribing. However, it involves an initial outlay of money that is currently not being spent and many national governments, in both rich and poor countries, are unwilling to incur extra costs.
The complete article is available as a provisional PDF. The fully formatted PDF and HTML versions are in production.

Health Affairs
July 2012; Volume 31, Issue 7
http://content.healthaffairs.org/content/current
Theme: Assessing The President's Emergency Plan For AIDS Relief

- From Emergency to Sustainability
- How Bush Dramatically Expanded US Response
- Toward An AIDS-Free Generation
- Building on the Scientific Progress
- Applying PEPFAR's Lessons to the US
- The Global Health Strategy of HHS
- PEPFAR's Public and Private Partnerships
- Antiretroviral Drugs: Treatment As Prevention
- Eliminating Mother-to-Child HIV Transmission
- The "Third Wave" of HIV Prevention
- A Clinician's Experience In Nigeria
- Collaborating With the Global Fund
- View Table of Contents

Given Financial Constraints, It Would Be Unethical To Divert Antiretroviral Drugs From Treatment To Prevention
Ruth Macklin and Ethan Cowan
Abstract
Striking advances in HIV prevention have set the stage for renewed debate on setting priorities in the fight against HIV/AIDS. Two new prevention strategies—preexposure prophylaxis and treatment as prevention—use antiretroviral drugs for prevention of HIV/AIDS in addition to treating patients. The potential for success of these new prevention strategies sets up an ethical dilemma: where resources are limited and supplies of lifesaving antiretroviral medications are insufficient to treat those currently living with HIV, how should these resources be divided between treatment and prevention? This article explores several ethical principles used in formulating public health policy. Assuming that limited resources are available for spending on drugs, we conclude that it would be unethical to watch patients with treatable AIDS worsen and die, even with supportive care, so that medications for treatment can be diverted for prevention.

Health and Human Rights
Vol 14, No 1 (2012)
http://hhrjournal.org/index.php/hhr
[Reviewed earlier]

Health Economics, Policy and Law
Volume 7 - Issue 03 - July 2012
http://journals.cambridge.org/action/displayIssue?jid=HEP&tab=currentissue
Articles
Incentives, health promotion and equality

Kristin Voigt
Department of Politics, Philosophy & Religion, Lancaster University, Lancaster, UK
Abstract
The use of incentives to encourage individuals to adopt 'healthier' behaviours is an increasingly popular instrument in health policy. Much of the literature has been critical of 'negative' incentives, often due to concerns about equality; 'positive' incentives, however, have largely been welcomed as an instrument for the improvement of population health and possibly the reduction of health inequalities. The aim of this paper is to provide a more systematic assessment of the use of incentives from the perspective of equality. The paper begins with an overview of existing and proposed incentive schemes. I then suggest that the distinction between 'positive' and 'negative' incentives – or 'carrots' and 'sticks' – is of limited use in distinguishing those incentive schemes that raise concerns of equality from those that do not. The paper assesses incentive schemes with respect to two important considerations of equality: equality of access and equality of outcomes. While our assessment of incentive schemes will, ultimately, depend on various empirical facts, the paper aims to advance the debate by identifying some of the empirical questions we need to ask. The paper concludes by considering a number of trade-offs and caveats relevant to the assessment of incentive schemes.

Health Policy and Planning
Volume 27 Issue 4 July 2012
http://heapol.oxfordjournals.org/content/current
[Reviewed earlier]

Human Vaccines & Immunotherapeutics (formerly Human Vaccines)
Volume 8, Issue 7 July 2012
http://www.landesbioscience.com/journals/vaccines/toc/volume/8/issue/7/
[Reviewed earlier]

International Journal of Infectious Diseases
Volume 16, Issue 7, Pages e469-e572 (July 2012)
http://www.sciencedirect.com/science/journal/12019712
[Reviewed earlier]

JAMA
July 11, 2012, Vol 308, No. 2
http://jama.ama-assn.org/current.dtl
Viewpoint
The Moral Duty to Buy Health Insurance
Tina Rulli, PhD; Ezekiel J. Emanuel, MD, PhD; David Wendler, PhD
Extract [Free full text]
The 2010 Patient Protection and Affordable Care Act (ACA) was designed to increase health insurance coverage in the United States. Its most controversial feature is the requirement that US residents purchase health insurance or pay a financial penalty.

Although debate focuses on the constitutionality of this individual mandate, the central concern is a moral matter—is it morally appropriate to require individuals to purchase health insurance?

Proponents argue that a mandate could lower insurance premiums for everyone by pooling individuals with varying health risks. Opponents respond that requiring people to contribute to the collective good is inconsistent with respect for individual liberty. Appeal to the collective good could justify requiring individuals to buy gym memberships or eat broccoli.1

Rather than appeal to the collective good, this Viewpoint argues for a duty to buy health insurance based on the moral duty individuals have to reduce certain burdens they pose on others. Because physicians and hospitals have a duty to rescue the uninsured by providing acute and emergency care, individuals have a corresponding duty to purchase insurance to cover the costs of this care. Requiring individuals to meet this obligation is consistent with respect for individual liberty and does not imply that they must buy gym memberships or eat broccoli….

Viewpoint | July 11, 2012 ONLINE FIRST

Ending Preventable Child Death in a Generation

Roger I. Glass, MD, PhD; Alan E. Guttmacher, MD; Robert E. Black, MD

Extract [Free full text]

During the past 20 years, there has been a substantial decline in mortality among children younger than 5 years from 12.0 million deaths in 1990 to 7.6 million in 2010.1 In these decades alone, global health and development efforts have saved the lives of more than 50 million children, half of them by preventing deaths due to pneumonia, diarrhea, and measles.2 This improvement in child survival was catalyzed in part by setting aspirational global targets such as the Millennium Development Goals (MDGs).3

As 2015 approaches, and with it a final assessment of progress toward MDG 4 on reducing child mortality, it is appropriate to consider a post-2015 vision for child health. A new common vision for a global commitment to end all preventable child deaths is needed. Such a vision will not be compelling unless it can be tied to concrete and measurable benchmarks at the global and country levels that are both ambitious and plausible. In this Viewpoint, a new benchmark is detailed: that all countries achieve a national under-5 mortality rate (U5MR) of no more than 20 deaths per 1000 live births by 2035 and that the global average U5MR should decline to 15 deaths per 1000 in 2035. Of 195 countries, 98 already have U5MRs of 20 per 1000 or fewer; 43 countries would be expected to reach this goal by 2035 at current annual rates of reduction (ARRs), and 54 countries would have to accelerate progress above the 2000-2010 ARRs.4

Original Contribution | July 11, 2012

Risk of Guillain-Barré Syndrome Following H1N1 Influenza Vaccination in Quebec

Philippe De Wals, PhD; Geneviève Deceuninck, MD; Eveline Toth, MSc; Nicole Boulianne, MSc; Denis Brunet, MD; Renée-Myriam Boucher, MD; Monique Landry, MD; Gaston De Serres, PhD

Abstract

Context In fall 2009 in Quebec, Canada, an immunization campaign was launched against the 2009 influenza A(H1N1) pandemic strain, mostly using an AS03 adjuvant vaccine. By the end of the year, 57% of the 7.8 million residents had been vaccinated.

Objective To assess the risk of Guillain-Barré syndrome (GBS) following pandemic influenza vaccine administration.

Design Population-based cohort study with follow-up over the 6-month period October 2009 through March 2010. The investigation was ordered by the chief medical officer of health in accordance with the Quebec Public Health Act.

Setting All acute care hospitals and neurology clinics in Quebec.

Population Suspected and confirmed GBS cases reported by physicians, mostly neurologists, during active surveillance or identified in the provincial hospital summary discharge database. Medical records were reviewed and cases classified according to Brighton Collaboration definitions (categorized as level 1, 2, or 3, corresponding to criteria of decreasing certainty in diagnosis). Immunization status was verified and denominators were estimated from the provincial immunization registry (4.4 million vaccinated) and census data (total target population aged ≥6 months, 7.8 million), with a total of 3 623 046 person-years of observation.

Main Outcome Measures Relative and attributable risks were calculated using a Poisson model and the self-controlled case-series method.

Results Over a 6-month period, 83 confirmed GBS cases were identified, including 71 Brighton level 1 through 3 cases. Twenty-five confirmed cases had been vaccinated against 2009 influenza A(H1N1) 8 or fewer weeks before disease onset, with most (19/25) vaccinated 4 or fewer weeks before onset. In the Poisson model, the age- and sex-adjusted relative risk was 1.80 (95% CI, 1.12-2.87) for all confirmed cases during the 8-week postvaccination period and was 2.75 (95% CI, 1.63-4.62) during the 4-week postvaccination period. Using the self-controlled case-series method, relative risk estimates during the 4-week postvaccination period were 3.02 (95% CI, 1.64-5.56) for all confirmed cases (n = 42) and 2.33 (95% CI, 1.19-4.57) for Brighton level 1 through 3 cases (n = 36). The number of GBS cases attributable to vaccination was approximately 2 per 1 million doses. There was no indication of an excess risk in persons younger than 50 years.

Conclusions In Quebec, the 2009 influenza A(H1N1) vaccine was associated with a small but significant risk of GBS. It is likely that the benefits of immunization outweigh the risks.

Guillain-Barré syndrome (GBS) is a peripheral neuropathy with acute onset and is characterized, in its typical presentation, by rapidly developing motor weakness and areflexia.[1 - 2] The disease is thought to be autoimmune and triggered by a stimulus of external origin.[1 - 2] In 1976-1977, an unusually high rate of GBS was identified in the United States following the administration of inactivated "swine" influenza A(H1N1) vaccines.[3] In 2003, the Institute of Medicine (IOM) concluded that the evidence favored acceptance of a causal relationship between the 1976 swine influenza vaccines and GBS in adults.[4] Studies of seasonal influenza vaccines administered in subsequent years have found small or no increased risk.[5] In mice, different influenza vaccines can induce antiganglioside antibodies that are associated with the development of GBS in humans.[6] Extrapolation of results of animal studies to humans, however, is difficult. In a more recent assessment of epidemiologic studies on seasonal influenza vaccines, experimental studies in animals, and case reports in humans, the IOM Committee to Review Adverse Effects of Vaccines concluded that the evidence was inadequate to accept or reject a causal relationship.[7]

In the province of Quebec, Canada, a mass immunization campaign was launched in the fall of 2009 to control a pandemic caused by a new influenza A(H1N1) virus.[8 - 9] Herein

we report results of a population-based epidemiologic investigation ordered by the chief medical officer of health, based on GBS cases notified to public health authorities and others found in the MEDECHO provincial hospitalization database.

Editorial | July 11, 2012

Influenza Pandemics—Pregnancy, Pathogenesis, and Perinatal Outcomes

Mark C. Steinhoff, MD; Noni E. MacDonald, MD, MSc, FRCPC

Extract [Free full text]

Since the 1918 influenza pandemic, it has been clear that pandemic influenza is associated with increased morbidity and mortality in pregnancy, and more recent studies have shown that nonpandemic seasonal influenza strains also lead to morbidity for pregnant women and their infants.1 In the 2009 worldwide pandemic of influenza A(H1N1)pdm09, pregnant women were at high risk for severe complications, including death and intensive care unit admission.2

The adverse effects of antenatal influenza infection on pregnant women and their infants suggest a biological effect of influenza infection in the mother that compromises the fetus. These effects are rarely associated with direct infection of the fetus with influenza virus, although fetal infection has been reported infrequently during epidemics, pandemics,3 - 4 and with the H5N1 influenza strain.5 Instead, it appears that the normal pregnancy-associated immunologic changes may inhibit the inflammatory response to influenza virus infection in pregnancy,6 leading to increased risks to mother and infant. Because of these observations, pregnant women have been listed among high-risk groups for seasonal influenza vaccine in the United States since 1997, and safety data suggest these vaccines are safe in pregnancy.7 - 8 Pregnant women were prioritized for immunization during the 2009 influenza A(H1N1)pdm09 pandemic, despite limited data on the safety of pandemic influenza vaccines in pregnancy.

In this issue of JAMA, Pasternak and colleagues9 report the results of an observational cohort study on the safety in pregnancy of the monovalent inactivated ASO3-adjuvanted split virion influenza A(H1N1)pdm09 vaccine…

Original Contribution | July 11, 2012

Risk of Adverse Fetal Outcomes Following Administration of a Pandemic Influenza A(H1N1) Vaccine During Pregnancy

Björn Pasternak, MD, PhD; Henrik Svanström, MSc; Ditte Mølgaard-Nielsen, MSc; Tyra G. Krause, MD, PhD; Hanne-Dorthe Emborg, DVM; Mads Melbye, MD, DrMedSci; Anders Hviid, MSc, DrMedSci

Abstract

Context Assessment of the fetal safety of vaccination against influenza A(H1N1)pdm09 in pregnancy has been limited.

Objective To investigate whether exposure to an adjuvanted influenza A(H1N1)pdm09 vaccine during pregnancy was associated with increased risk of adverse fetal outcomes.

Design, Setting, and Participants Registry-based cohort study based on all liveborn singleton infants in Denmark, delivered between November 2, 2009, and September 30, 2010. In propensity score–matched analyses, we estimated prevalence odds ratios (PORs) of adverse fetal outcomes, comparing infants exposed and unexposed to an AS03-adjuvanted influenza A(H1N1)pdm09 vaccine during pregnancy.

Main Outcome Measures Major birth defects, preterm birth, and small size for gestational age.

Results From a cohort of 53,432 infants (6989 [13.1%] exposed to the influenza A[H1N1]pdm09 vaccine during pregnancy [345 in the first trimester and 6644 in the second or third trimester]), 660 (330 exposed) were included in propensity score–matched analyses of adverse fetal outcomes associated with first-trimester exposure. For analysis of small size for gestational age after second- or third-trimester exposure, 13 284 (6642 exposed) were included; for analyses of preterm birth, 12,909 (6543 exposed) were included. A major birth defect was diagnosed in 18 of 330 infants (5.5%) exposed to the vaccine in the first trimester, compared with 15 of 330 unexposed infants (4.5%) (POR, 1.21; 95% CI, 0.60-2.45). Preterm birth occurred in 31 of 330 infants (9.4%) exposed in the first trimester, compared with 24 of 330 unexposed infants (7.3%) (POR, 1.32; 95% CI, 0.76-2.31), and in 302 of 6543 infants (4.6%) with second- or third-trimester exposure, compared with 295 of 6366 unexposed infants (4.6%) (POR, 1.00; 95% CI, 0.84-1.17). Small size for gestational age was observed in 25 of 330 infants (7.6%) with first-trimester exposure compared with 31 of 330 unexposed infants (9.4%) (POR, 0.79; 95% CI, 0.46-1.37), and in 641 of 6642 infants (9.7%) with second- or third-trimester exposure, compared with 657 of 6642 unexposed infants (9.9%) (POR, 0.97; 95% CI, 0.87-1.09).

Conclusions In this Danish cohort, exposure to an adjuvanted influenza A(H1N1)pdm09 vaccine during pregnancy was not associated with a significantly increased risk of major birth defects, preterm birth, or fetal growth restriction.

Journal of Health Organization and Management
Volume 26 issue 5 Published: 2012
http://www.emeraldinsight.com/journals.htm?issn=1477-7266&show=latest
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Volume 206 Issue 3 August 1, 2012
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[No relevant content]

Journal of Global Infectious Diseases (JGID)
April-June 2012 Volume 4 | Issue 2 Page Nos. 99-138
http://www.jgid.org/currentissue.asp?sabs=n
[Reviewed earlier; No relevant content]

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July 2012; 61 (Pt 7)
http://jmm.sgmjournals.org/content/current
[Reviewed earlier]

The Lancet
Jul 14, 2012 Volume 380 Number 9837 p75 – 186 e1

http://www.thelancet.com/journals/lancet/issue/current

Articles

Equity in financing and use of health care in Ghana, South Africa, and Tanzania: implications for paths to universal coverage

Anne Mills, John E Ataguba, James Akazili, Jo Borghi, Bertha Garshong, Suzan Makawia, Gemini Mtei, Bronwyn Harris, Jane Macha, Filip Meheus, Di McIntyre

Summary

Background

Universal coverage of health care is now receiving substantial worldwide and national attention, but debate continues on the best mix of financing mechanisms, especially to protect people outside the formal employment sector. Crucial issues are the equity implications of different financing mechanisms, and patterns of service use. We report a whole-system analysis—integrating both public and private sectors—of the equity of health-system financing and service use in Ghana, South Africa, and Tanzania.

Methods

We used primary and secondary data to calculate the progressivity of each health-care financing mechanism, catastrophic spending on health care, and the distribution of health-care benefits. We collected qualitative data to inform interpretation.

Findings

Overall health-care financing was progressive in all three countries, as were direct taxes. Indirect taxes were regressive in South Africa but progressive in Ghana and Tanzania. Out-of-pocket payments were regressive in all three countries. Health-insurance contributions by those outside the formal sector were regressive in both Ghana and Tanzania. The overall distribution of service benefits in all three countries favoured richer people, although the burden of illness was greater for lower-income groups. Access to needed, appropriate services was the biggest challenge to universal coverage in all three countries.

Interpretation

Analyses of the equity of financing and service use provide guidance on which financing mechanisms to expand, and especially raise questions over the appropriate financing mechanism for the health care of people outside the formal sector. Physical and financial barriers to service access must be addressed if universal coverage is to become a reality.

Funding

European Union and International Development Research Centre.

The Lancet Infectious Disease

Jul 2012 Volume 12 Number 7 p497 - 576

http://www.thelancet.com/journals/laninf/issue/current

[Reviewed earlier]

Online First

Cambodian outbreak tests International Health Regulations

The Lancet Infectious Diseases

Extract

The news that emerged from Cambodia in the first week of July of an unknown fatal illness that had killed at least 60 children in the previous 3 months, and the subsequent interagency response, shows how the International Health Regulations (IHRs) can work

in practice. The event also serves as a timely reminder of the progress that still needs to be made to implement the IHR provisions in all WHO member states…

Medical Decision Making (MDM)
May–June 2012; 32 (3)
http://mdm.sagepub.com/content/current
[Reviewed earlier]

The Milbank Quarterly
June 2012 Volume 90, Issue 2 Pages 215–416
http://onlinelibrary.wiley.com/doi/10.1111/milq.2012.90.issue-2/issuetoc
[Reviewed earlier]

Nature
Volume 487 Number 7406 pp139-266 12 July 2012
http://www.nature.com/nature/current_issue.html
Editorial: Take a stand
doi:10.1038/487139b
Published online
11 July 2012
Legal actions and oversight are necessary to keep the drug industry in line.

Nature Immunology
July 2012, Volume 13 No 7 pp623-702
http://www.nature.com/ni/journal/v13/n7/index.html
[Reviewed earlier; No relevant content]

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July 2012, Volume 18 No 7 pp989-1153
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July 2012 Vol 12 No 7
http://www.nature.com/nri/journal/v12/n7/index.html
[Reviewed earlier]

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July 12, 2012 Vol. 367 No. 2
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[No relevant content]

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July 2012 - Volume 31 - Issue 7 pp: A7-A8,667-794,e92-e98
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[Reviewed earlier]

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July 2012, VOLUME 130 / ISSUE 1
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[Reviewed earlier]

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July 1, 2012 - Volume 30 - Issue 7 pp: 537-631
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[Reviewed earlier; No relevant content]

PLoS One
[Accessed 14 July 2012]
http://www.plosone.org/article/browse.action;jsessionid=577FD8B9E1F322DAA533C413369CD6F3.ambra01?field=date
Mathematical Modelling Long-Term Effects of Replacing Prevnar7 with Prevnar13 on Invasive Pneumococcal Diseases in England and Wales
Yoon Hong Choi, Mark Jit, Stefan Flasche, Nigel Gay, Elizabeth Miller
PLoS ONE: Research Article, published 13 Jul 2012 10.1371/journal.pone.0039927
Abstract
Introduction
England and Wales recently replaced the 7-valent pneumococcal conjugate vaccine (PCV7) with its 13-valent equivalent (PCV13), partly based on projections from mathematical models of the long-term impact of such a switch compared to ceasing pneumococcal conjugate vaccination altogether.
Methods
A compartmental deterministic model was used to estimate parameters governing transmission of infection and competition between different groups of pneumococcal serotypes prior to the introduction of PCV13. The best-fitting parameters were used in an individual based model to describe pneumococcal transmission dynamics and effects of various options for the vaccination programme change in England and Wales. A number of scenarios were conducted using (i) different assumptions about the number of invasive pneumococcal disease cases adjusted for the increasing trend in disease

incidence prior to PCV7 introduction in England and Wales, and (ii) a range of values representing serotype replacement induced by vaccination of the additional six serotypes in PCV13.

Results

Most of the scenarios considered suggest that ceasing pneumococcal conjugate vaccine use would cause an increase in invasive pneumococcal disease incidence, while replacing PCV7 with PCV13 would cause an overall decrease. However, the size of this reduction largely depends on the level of competition induced by the additional serotypes in PCV13. The model estimates that over 20 years of PCV13 vaccination, around 5000–62000 IPD cases could be prevented compared to stopping pneumococcal conjugate vaccination altogether.

Conclusion

Despite inevitable uncertainty around serotype replacement effects following introduction of PCV13, the model suggests a reduction in overall invasive pneumococcal disease incidence in all cases. Our results provide useful evidence on the benefits of PCV13 to countries replacing or considering replacing PCV7 with PCV13, as well as data that can be used to evaluate the cost-effectiveness of such a switch.

Vaccination Behaviour Influences Self-Report of Influenza Vaccination Status: A Cross-Sectional Study among Health Care Workers

Anna Llupià, Alberto L. García-Basteiro, Guillermo Mena, José Ríos, Joaquim Puig, José M. Bayas, Antoni Trilla

PLoS ONE: Research Article, published 11 Jul 2012 10.1371/journal.pone.0039496

Abstract

Background

Published influenza vaccination coverage in health care workers (HCW) are calculated using two sources: self-report and vaccination records. The objective of this study was to determine whether self-report is a good proxy for recorded vaccination in HCW, as the degree of the relationship is not known, and whether vaccine behaviour influences self-reporting.

Methods

A cross-sectional study was conducted using a self-administered survey during September 2010. Considering the vaccination record as the gold standard of vaccination, the properties of self-report as a proxy of the record (sensitivity, specificity, positive predictive value, negative predictive value) were calculated. Concordance between the vaccination campaigns studied (2007–2010) was made using the Kappa index, and discordance was analyzed using McNemar's test.

Results

248 HCW responded. The 95% confidence intervals of coverage according to the vaccination record and to self-report overlapped, except for 2007, and the Kappa index showed a substantial concordance, except for 2007. McNemar's test suggested that differences between discordant cases were not due to chance and it was found that the proportion of unvaccinated discordant cases was higher than that of vaccinated discordant cases.

Conclusions

In our study population, self-reported influenza vaccination coverage in HCW in the previous two years is a good proxy of the vaccination record. However, vaccination behaviour influences the self-report and explains a trend to overestimate coverage in

self-reporting compared to the vaccination record. The sources of coverage should be taken into account whenever comparisons are made.

Knowledge and Acceptability of Pap Smears, Self-Sampling and HPV Vaccination among Adult Women in Kenya

Anne F. Rositch, Ann Gatuguta, Robert Y. Choi, Brandon L. Guthrie, Romel D. Mackelprang, Rose Bosire, Lucy Manyara, James N. Kiarie, Jennifer S. Smith, Carey Farquhar screening

PLoS ONE: Research Article, published 10 Jul 2012 10.1371/journal.pone.0040766

Abstract

Objectives

Our study aimed to assess adult women's knowledge of human papillomavirus (HPV) and cervical cancer, and characterize their attitudes towards potential screening and prevention strategies.

Methods

Women were participants of an HIV-discordant couples cohort in Nairobi, Kenya. An interviewer-administered questionnaire was used to obtain information on sociodemographic status, and sexual and medical history at baseline and on knowledge and attitudes towards Pap smears, self-sampling, and HPV vaccination at study exit.

Results

Only 14% of the 409 women (67% HIV-positive; median age 29 years) had ever had a Pap smear prior to study enrollment and very few women had ever heard of HPV (18%). Although most women knew that Pap smears detect cervical cancer (69%), very few knew that routine Pap screening is the main way to prevent ICC (18%). Most women reported a high level of cultural acceptability for Pap smear screening and a low level of physical discomfort during Pap smear collection. In addition, over 80% of women reported that they would feel comfortable using a self-sampling device (82%) and would prefer at-home sample collection (84%). Nearly all women (94%) reported willingness to be vaccinated to prevent cervical cancer if offered at no or low cost.

Conclusions

These findings highlight the need to educate women on routine use of Pap smears in the prevention of cervical cancer and demonstrate that vaccination and self-sampling would be acceptable modalities for cervical cancer prevention and screening.

PLoS Medicine

(Accessed 14 July 2012)

http://www.plosmedicine.org/article/browse.action?field=date

[No new relevant data]

PLoS Neglected Tropical Diseases

June 2012

http://www.plosntds.org/article/browseIssue.action

[Reviewed earlier]

PNAS - Proceedings of the National Academy of Sciences of the United States of America

(Accessed 14 July 2012)
http://www.pnas.org/content/early/recent

Stabilization of vaccines and antibiotics in silk and eliminating the cold chain

Jeney Zhanga,b,1, Eleanor Pritcharda,1, Xiao Hua, Thomas Valentina, Bruce Panilaitisa, Fiorenzo G. Omenettoa, and David L. Kaplana,2
+ Author Affiliations
aTufts University, Department of Biomedical Engineering, Medford, MA 02155; and
bTufts University, Department of Chemical & Biological Engineering, Medford, MA 02155
Edited by Arnold L. Demain, Drew University, Madison, NJ, and approved June 12, 2012 (received for review April 12, 2012)
Abstract
Sensitive biological compounds, such as vaccines and antibiotics, traditionally require a time-dependent "cold chain" to maximize therapeutic activity. This flawed process results in billions of dollars worth of viable drug loss during shipping and storage, and severely limits distribution to developing nations with limited infrastructure. To address these major limitations, we demonstrate self-standing silk protein biomaterial matrices capable of stabilizing labile vaccines and antibiotics, even at temperatures up to 60 °C over more than 6 months. Initial insight into the mechanistic basis for these findings is provided. Importantly, these findings suggest a transformative approach to the cold chain to revolutionize the way many labile therapeutic drugs are stored and utilized throughout the world.

Public Health Ethics
Volume 5 Issue 1 April 2012
http://phe.oxfordjournals.org/content/current
[Reviewed earlier]

Science
13 July 2012 vol 337, issue 6091, pages 125-256
http://www.sciencemag.org/current.dtl

Introduction to Special Issue: HIV/AIDS in America
Leslie Roberts
[Full text]

The epidemic of acquired immunodeficiency syndrome was first recognized in the United States. As clinicians from Los Angeles, California, reported in the 5 June 1981 issue of Morbidity and Mortality Weekly Report, they had seen odd immune problems and opportunistic infections in five young "active homosexuals." Similar reports soon came in from all over the country and the world, making it clear that AIDS affected heterosexuals and homosexuals alike and also spread from mother to child and via tainted blood products and dirty needles. In the following years, U.S. researchers helped prove that HIV causes the disease, which led to a critical blood test to detect the novel retrovirus. The U.S. National Institutes of Health and the Centers for Disease Control and Prevention—prodded by AIDS activists such as Mark Harrington of the Treatment Action Group (pictured here)—steadily ramped up support for basic research as well as efforts to develop and test treatment and prevention interventions. In the early 2000s,

the U.S. government poured billions of dollars into programs that now bring life-saving antiretrovirals to millions of people in cash-strapped countries.

By any measure, the United States has played a vital global role in unraveling HIV's mysteries, providing help to the infected and protecting the vulnerable.

It may seem odd, then, that since 1990 this country has not hosted the International AIDS Conference, a megameeting that has gathered 20,000 participants every other year. But that will change on 22 to 27 July, when the gathering will take place in Washington, D.C. The meeting organizers shunned the United States because of an immigration ban on HIV-infected people imposed by Congress in 1987, which President Barack Obama ended in 2010.

In keeping with that shift, Science is focusing this special HIV/AIDS issue on America, now home to an estimated 1.2 million HIV-infected people—many of whom have little in common with the original five gay men in Los Angeles. The Deep South has become the epicenter; blacks—gay and straight—face a far higher risk of becoming infected than whites, and poverty is a major driver for all races. The biggest challenge the country faces today is diagnosing all of its HIV-infected people and helping them take full advantage of the existing treatments, which both stave off disease and make people less infectious. It is a problem shared worldwide.

Correspondent Jon Cohen, working with photographers Malcolm Linton and Darrow Montgomery, visited 10 U.S. cities this spring, and the package of stories that begins on p. 168 describes the varied epidemics and responses. A News Focus by Cohen spends a day with Anthony Fauci, who leads the NIH branch that funds more HIV/AIDS researchers than any institution in the world (p. 152). This special issue also includes an Editorial by Salim Abdool Karim (p. 133), who highlights problems rolling out what's known as pre-exposure prophylaxis, as well as an update on HIV antibody research by Dennis Burton and colleagues (p. 183) that promises to inform AIDS vaccine development. Online, a slideshow offers more images and stories about the country's epidemic, and Science Careers features profiles of two young HIV/AIDS public health workers making a big dent in big-city epidemics.

Science Translational Medicine
11 July 2012 vol 4, issue 142
http://stm.sciencemag.org/content/current
[No relevant content]

Tropical Medicine & International Health
July 2012 Volume 17, Issue 7 Pages 795–933
http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1365-3156/currentissue
[Reviewed earlier]

Vaccine
http://www.sciencedirect.com/science/journal/0264410X
Volume 30, Issue 33 pp. 4897-5058 (13 July 2012)
Reviews

Acellular pertussis vaccine use in risk groups (adolescents, pregnant women, newborns and health care workers): A review of evidences and recommendations

Review Article
Pages 5179-5190
Angela Bechini, Emilia Tiscione, Sara Boccalini, Miriam Levi, Paolo Bonanni
Abstract
Background
Pertussis is an acute infectious illness, caused by the bacteria Bordetella pertussis and commonly known as "whooping cough". Waning immunity after vaccination or after natural infection contributes significantly to the increasing incidence rates in adolescents and adults. Prevention of pertussis in industrialized countries is mainly based on immunization with acellular vaccines in combination with other antigens. A booster dose with an adult-formulation tetanus-diphtheria toxoid and acellular pertussis vaccine (Tdap) is now recommended for all adolescents by several countries, and replacement of the decennial Td dose with a single or more doses of Tdap is recommended for adults.
Objective
Our review aims at describing the current knowledge on the impact of acellular pertussis vaccination in adolescents and adults, with particular focus on specific risk groups: adolescents, pregnant women and their newborns, and health care workers (HCWs), and secondly at suggesting possible immunization strategies.
Methods
Data were retrieved by searches of Pubmed, references, from relevant articles and open-access websites.
Results
In countries where an adolescent booster dose was adopted, a certain decrease of incidence rates was observed. No serologic correlate of protection after immunization exists, but subjects with high antibody levels against pertussis antigens are less likely to develop the disease. Tdap vaccine was demonstrated to induce antibodies to pertussis antigens exceeding those associated with efficacy in infants, in both adolescents and adults. Tdap use in pregnant women seems to be safe and might represent a useful tool in order to prevent pertussis cases in the first months of life. Neonatal immunization with monovalent acellular pertussis vaccine can efficiently prime T and B cells and act as a basis for future immune responses. Cocooning strategies involving all those surrounding newborns have started to be implemented. Their impact on infant pertussis cases will be evaluated in the coming years. Coverage in HCWs should be increased, given their important role in pertussis transmission in health care settings.
Conclusions
Despite the more recent position paper of WHO gives priority to infant and childhood vaccination against pertussis and leaves adolescent, adult and risk group immunization as an option for the future, data are quickly accumulating to support the need to consider pertussis vaccination as a crucial preventative intervention even in adolescents and special risk groups.

Malaria vaccines: Focus on adenovirus based vectors

Review Article
Pages 5191-5198
Nathaniel J. Schuldt, Andrea Amalfitano

Abstract
Protection against malaria through vaccination is known to be achievable, as first demonstrated over 30 years ago. Vaccination via repeated bites with Plasmodium falciparum infected and irradiated mosquitoes provided short lived protection from malaria infection to these vaccinees. Though this method still remains the most protective malaria vaccine to date, it is likely impractical for widespread use. However, recent developments in sub-unit malaria vaccine platforms are bridging the gap between high levels of protection and feasibility. The current leading sub-unit vaccine, RTS,S (which consists of a fusion of a portion of the P. falciparum derived circumsporozoite protein to the Hepatitis B surface antigen), has demonstrated the ability to induce protection from malaria infection in up 56% of RTS,S vaccinees. Though encouraging, these results may fall short of protection levels generally considered to be required to achieve eradication of malaria. Therefore, the use of viral vectored vaccine platforms has recently been pursued to further improve the efficacy of malaria targeted vaccines. Adenovirus based vaccine platforms have demonstrated potent anti-malaria immune responses when used alone, as well when utilized in heterologous prime boost regimens. This review will provide an update as to the current advancements in malaria vaccine development, with a focus on the use of adenovirus vectored malaria vaccines.

Regular Papers

Assessing potential introduction of universal or targeted hepatitis A vaccination in the Netherlands

Original Research Article
Pages 5199-5205
A.W.M. Suijkerbuijk, A.K. Lugnér, W. van Pelt, J. Wallinga, L.P.B. Verhoef, H.E. de Melker, G.A. de Wit
Abstract
In many industrialized countries, hepatitis A incidence rates have declined steadily in the past decades. Since future cohorts of non-vaccinated elderly will lack protection against disease and the burden of hepatitis A is higher with increasing age, this could be an argument in favour of taking preventive measures such as including hepatitis A vaccine into the National Immunisation Program, or offering hepatitis A vaccine to the elderly only. Using a vaccination evaluation scheme, we assessed the potential benefits and drawbacks of introducing hepatitis A vaccine in the National Immunisation Program in the Netherlands. The average number of annual hepatitis A notifications is declining, from 957 in the period 1991 to 1995 to 211 over the period 2006 to 2010. The direct health care costs and costs due to productivity losses per patient are rising, because the age at infection increases and older patients require a relatively higher number of hospitalizations. Initiating a vaccination program would most likely not be cost-effective yet. The annual costs of mass-vaccination are large: about €10 million for infants and €13 million for older people (and only in the first year €210 million), based on current retail prices. The annual effects of mass-vaccination are small: the cost-of-illness in recent years attributed to hepatitis A infection is estimated to be €650,000 per year, and the disease burden is on average 17 DALYs. Given the current low hepatitis A incidence, and the continuing decline in incidence, targeted preventive measures such as vaccinating travellers and other high-risk groups and timely vaccination of close contacts of hepatitis A patients are adequate. However, because susceptibility to hepatitis A is increasing in the group with the highest risk of developing severe complications upon infections, careful monitoring of the epidemiology of hepatitis A remains important.

Prevalence of type-specific human papillomavirus infection among women in France: Implications for screening, vaccination, and a future generation of multivalent HPV vaccines

Original Research Article
Pages 5215-5221
Joseph Monsonego, Laurent Zerat, Kari Syrjänen, Jean-Claude Zerat, Jennifer S. Smith, Philippe Halfon
Abstract
To assess human papillomavirus (HPV) prevalence and genotype distribution by age and cervical cytology/histology status among women undergoing routine gynecological examinations, and to discuss the possible impact on preventive strategies. Liquid-based cytology (LBC) samples were tested for HPV DNA, mRNA, and HPV genotypes. Women with atypical squamous cells of undetermined significance or greater (ASC-US+) and/or at least one positive HPV test were referred to colposcopy. Those with normal colposcopy results had biopsies taken at the 6 and 12 O'clock positions of the normal transformation zone. Of the 5002 women, 515 (10.3%) were <25 and 4487 (89.7%) were ≥25 years old. Overall HPV prevalence varied between 10.1% and 16.1% depending on the assay. Risk factors for HPV infection included greater number of recent sexual partners, history of abnormal cervical pathology, age <25 years, and smoking. HPV prevalence increased with the cytological and histological severity of cervical lesions. Prevalence of HPV 16/18 was 5.2% and 2.7% in women <25 and ≥25 years old, respectively. HPV 16 was the type most strongly associated with a diagnosis of cervical intraepithelial neoplasia grade 3 or higher (CIN3+) (odds ratio = 11.64 vs. HPV 16 absent, $P < 0.001$). A high proportion of high-grade cervical lesions (60.6% of genotyping assay-positive CIN2+) were associated with HPV types 31, 33, 45, 52, or 58. These data indicate that almost all young women could benefit from HPV prophylactic vaccination, but confirm the need for continued cervical screening and highlight the potential benefit of future vaccines targeting a wider range of HPV types.

Variation in adult vaccination policies across Europe: An overview from VENICE network on vaccine recommendations, funding and coverage

Original Research Article
Pages 5222-5228
Elisabeth E. Kanitz, Lauren A. Wu, Cristina Giambi, Raymond A. Strikas, Daniel Levy-Bruhl, Pawel Stefanoff, Jolita Mereckiene, Eva Appelgren, Fortunato D'Ancona, VENICE (Vaccine European New Integrated Collaboration Effort) National Gatekeepers, Contact Points
Abstract
Background
In 2010–2011, in the framework of the VENICE project, we surveyed European Union (EU) and Economic Area (EEA) countries to fill the gap of information regarding vaccination policies in adults. This project was carried out in collaboration with the United States National Vaccine Program Office, who conducted a similar survey in all developed countries.
Methods
VENICE representatives of all 29 EU/EEA-countries received an online questionnaire including vaccination schedule, recommendations, funding and coverage in adults for 17 vaccine-preventable diseases.
Results

The response rate was 100%. The definition of age threshold for adulthood for the purpose of vaccination ranged from 15 to 19 years (median = 18 years). EU/EEA-countries recommend between 4 and 16 vaccines for adults (median = 11 vaccines). Tetanus and diphtheria vaccines are recommended to all adults in 22 and 21 countries respectively. The other vaccines are mostly recommended to specific risk groups; recommendations for seasonal influenza and hepatitis B exist in all surveyed countries. Six countries have a comprehensive summary document or schedule describing all vaccines which are recommended for adults. None of the surveyed countries was able to provide coverage estimates for all the recommended adult vaccines.
Conclusions
Vaccination policies for adults are not consistent across Europe, including the meaning of "recommended vaccine" which is not comparable among countries. Coverage data for adults should be collected routinely like for children vaccination.

Monitoring adverse events following immunization with a new conjugate vaccine against group A meningococcus in Niger, September 2010

Original Research Article
Pages 5229-5234
Maman S. Chaibou, Harouna Bako, Laouali Salisou, Téné M. Yaméogo, Mariama Sambo, Sung Hye Kim, Mamoudou H. Djingarey, Patrick L.F. Zuber, William A. Perea, Lorenzo Pezzoli

Abstract
Introduction
MenAfriVac is a new conjugate vaccine against Neisseria meningitidis serogroup A, the major cause of meningitis outbreaks in sub-Saharan Africa. In Niger, the MenAfriVac introduction campaign was conducted in the District of Filingue, during September 2010, targeting 392,211 individuals aged 1–29 years. We set up an enhanced spontaneous surveillance system to monitor adverse events following immunization (AEFI) during the campaign period and 42 days thereafter.
Methods
All the 33 health centres of the district have been designated as surveillance units, which reported AEFIs on a daily basis to the health district headquarters. Health care workers were instructed to screen patients presenting with predefined conditions of interest and patients spontaneously presenting at units or at vaccination posts with complaints after vaccination. Cases were classified as serious (resulting in death, hospitalization or long-term disability) or minor. A National Expert Committee was established to determine if serious cases were causally associated with the vaccine.
Results
In total, 356,532 vaccine doses were administered. During 61 days of monitoring, 82 suspected AEFIs were reported: 16 severe and 66 minor. The cumulative incidence was of 23.0 per 100,000 doses. Among severe cases, 14 were classified as coincidences, one urticaria complicated by respiratory distress was classified as a probable vaccine reaction, and one death was unclassifiable because post-mortem information was unavailable. The number of units that reported at least one case was 19/33 (57.6%).
Conclusions
Although these results are limited by underreporting of cases, we did not identify safety concerns with MenAfriVac. The lessons learned from this experience should be used to reinforce the national pharmacovigilance system in Niger to make it complaint with international standards. In order to do so, we recommend using a lighter system for

routine; and conducting regular training and supervisory activities to increase its acceptance among local health workers.

Design and initiation of a study to assess the direct and indirect effects of influenza vaccine given to children in rural India

Original Research Article
Pages 5235-5239
Wayne Sullender, Karen Fowler, Anand Krishnan, Vivek Gupta, Lawrence H. Moulton, Kathryn Lafond, Marc-Alain Widdowson, Renu B. Lal, Shobha Broor

Abstract
The burden of disease due to influenza is not well characterized for children in developing countries and the effectiveness of available influenza vaccines in lower resource settings has not been established. We initiated a prospective, longitudinal, phase IV, household-randomized, controlled, observer-blinded three year study (2009–2011) in a rural community of India to measure the total and indirect household protective effects of immunizing children ages 6 months through 10 years with seasonal inactivated trivalent influenza vaccine (TIV) or a control vaccine (n = 3697). Active weekly surveillance was conducted year round with home visits for identification of febrile acute respiratory illness (FARI) conducted for all vaccine recipients and household members (n = 18,220). Nasal and throat swabs were collected from each FARI episode for influenza detection by real-time reverse transcription polymerase chain reaction. The primary outcome was reduction in laboratory confirmed influenza infections in the influenza vaccine versus control vaccine group, with secondary outcome assessing indirect effects among the entire study population. This report describes the study site, cluster study design, choice of study and control vaccines, and the initial enrollment in the study.

Vaccine: Development and Therapy
(Accessed 14 July 2012)
http://www.dovepress.com/vaccine-development-and-therapy-journal
[No new relevant content]

Value in Health
Vol 15 | No. 4 | June 2012
http://www.valueinhealthjournal.com/current
[Reviewed earlier]

World Journal of Vaccines
Volume 02, Number 01 (February 2012)
http://www.scirp.org/journal/Home.aspx?IssueID=1399#17225
[Reviewed earlier]

Media Watch

Beginning in June 2012, *Vaccines: The Week in Review* expanded to alert readers to substantive news, analysis and opinion from the general media on vaccines, immunization, global; public health and related themes. *Media Watch* is not intended to be exhaustive, but indicative of themes and issues CVERP is actively tracking. This section will grow from an initial base of newspapers, magazines and blog sources, and is segregated from *Journal Watch* above which scans the peer-reviewed journal ecology.

We acknowledge the Western/Northern bias in this initial selection of titles and invite suggestions for expanded coverage. Most publications require either a registration or a fee-based subscription for access. We will provide full-text where content is published without restriction.

Economist
http://www.economist.com/
Accessed 14 July 2012

Vaccine technology: No sow's ear
Jul 10th 2012, 14:41 by The Economist online
Coverage of the PNAS article about silk as a potential technology for addressing vaccine logistics issue around temperature (see PNAS and NIH treatment above)

Contraception and development: Opening the Gates
Jul 12th 2012, 13:53 by J.P. | LONDON

WHEN several heads of state, a dozen health ministers and hundreds of delegates piled into a conference centre in the middle of London on July 11th, there was a sound of broken barriers everywhere. The family-planning summit was the first big international meeting on birth control since a United Nations conference in Cairo in 1994, a sign that international attitudes seem to be changing towards a long-neglected subject. It was an indication that the British government, the joint sponsor of the meeting, is ploughing something of a lonely furrow in development at the moment. As Duncan Green, the head of research at Oxfam, has pointed out, this is a period of British exceptionalism. "The UK is pretty much alone among traditional donors," he writes, "in sticking to its promises to increase aid despite deep public spending cuts, and is simultaneously pushing ahead in the multilateral arena." In addition to the family-planning meeting, Britain will convene a "hunger summit" during the Olympic Games, and the prime minister, David Cameron, is one of three co-chairs of a UN panel to look at what comes after the millennium development goals. But in some ways the loudest sound of broken barriers comes from the summit's other sponsor, the Bill and Melinda Gates Foundation.

When the foundation began in 1994, Mr Gates's idea was that it would focus on areas neglected by others-vaccines not being financed by governments; complex crop research that was too long-term for governments or companies to contemplate. Where governments or the private sector were taking a lead, the idea was, the foundation would stay away.

But over time, that self-denying ordinance has proved hard to maintain. At first, the foundation concentrated mainly on diseases and health. But nutrition is one of the main determinants of health; agriculture is vital to nutrition-and the Gates foundation has ended up as one of the most important financiers of agricultural research today (especially into the crops of the poor, such as cassava and millet). Something similar seems to be happening with birth control. Family planning was part of the foundation's health programmes from the start. But its programmes were small and now are being

scaled up quickly. Perhaps more important, the summit shows that the modest "after-you-Claude" approach is hard to reconcile with an operation that paid out $2.4 billion in grants in 2010, making the Gates foundation the size of a medium-sized country donor, comparable to Australia or Belgium.

The family-planning summit was an example of the Gates foundation not merely filling in gaps left by others but acting to change the behaviour of countries. Donors have avoided or downplayed family planning for years, partly because of its former association with coercion, partly because of religious objections, especially to abortion, and partly because some developing-country governments have viewed it as white people coming to poor nations and telling them to have fewer children. But as evidence collected in the new edition of the Lancet, a medical journal, convincingly shows, family planning also has substantial, long-term health and economic benefits. The attitude of some developing countries has already started to change; Rwanda, Malawi, Tanzania and Nigeria have all launched or expanded family-planning programmes in the past few years. But it has taken the Gates foundation to team up with Britain to push western donors into a big expansion of official support: at the London summit, they promised $2.6 billion worth of aid, aiming to cut by more than half the number of women in developing countries without access to modern contraceptive methods.
http://www.economist.com/blogs/feastandfamine/2012/07/contraception-and-development

Financial Times
http://www.ft.com
Accessed 14 July 2012
[No new relevant content]

Foreign Affairs
http://www.foreignaffairs.com/
July/August 2012 Volume 91, Number 4
Accessed 14 July 2012
[No new relevant content]

Foreign Policy
http://www.foreignpolicy.com/
Accessed 14 July 2012
[No new relevant content]

The Guardian
http://www.guardiannews.com/
Accessed 14 July 2012
Global development
Measles vaccines by motorbike help Congolese children
guardian.co.uk, 11 Jul 2012
Chris Bird: Doctors staged Operation Easy Rider to deliver vaccines to children in a remote area of the Democratic Republic of the Congo as fast as possible
…Measles vaccines by motorbike help Congolese children … to the town of Misisi to pick up measles vaccines stored at the health centre there to start immunising all the eligible children who were admitted to the hospital. Serge and Albert, the hospital's doctors, and

I agreed we needed more information … Operation Easy Rider helped deliver vaccines to children in a remote area of the Democratic Republic of the Congo…

The Huffington Post
http://www.huffingtonpost.com/
Accessed 14 July 2012
[No new unique, relevant content]

New Yorker
http://www.newyorker.com/
Accessed 14 July 2012
July 12, 2011
Blog: News Desk
The C.I.A., Vaccines, and bin Laden
Ahh—the old phony-vaccination ruse. How does the C.I.A. come up with this stuff? On Monday we learned, from a report in the Guardian, that our vaunted intelligence community decided to use a staged vaccination...
by Michael Specter
Read more http://www.newyorker.com/search?qt=dismax&sort=score+desc&query=vaccine&submit=#ixzz20dpHqDC0

New York Times
http://www.nytimes.com/
Accessed 14 July 2012
C.I.A. Vaccine Ruse May Have Harmed Pakistan's War on Polio ...
4 days ago ... The team sent into Pakistan to obtain DNA from Osama bin Laden's family had an unintended consequence.
July 10, 2012 - By THE NEW YORK TIMES - World - India Ink

Washington Post
http://www.washingtonpost.com/
Accessed 14 July 2012
[No new unique, relevant content]

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